

CLAIMS

1. A method of labeling a pharmaceutical product having one or more active ingredients and one or more inactive ingredients comprising varying an amount of at least one of the one or more inactive ingredients over time and generating a product signature of the pharmaceutical product having the varied amount of the at least one of the one or more inactive ingredients.
2. The method of claim 1 wherein the product signature comprises a near-infrared (NIR) spectra, and wherein the product signature comprises a label.
3. A batch identification method for determining the source of a pharmaceutical product from among a plurality of production batches of the pharmaceutical product, where the pharmaceutical product has one or more active ingredients and one or more inactive ingredients, comprising changing an amount of at least one of the one or more inactive ingredients among different batches of the pharmaceutical product produced, the variation being at least sufficient to distinguish the difference in the NIR spectra of product produced in each batch.
4. The method of claim 1, wherein the inactive ingredient whose amount is varied is selected from the group consisting of a filler, a disintegrant, a binder, a lubricant, a glidant, a film coat and combinations thereof.
5. The method of claim 4, wherein the inactive ingredient is the filler.
6. The method of claim 5, wherein the amount changed is in the range of about 5 percent based on a total weight of the product.
7. The method of claim 4 in which the inactive ingredient is the binder.
8. The method of claim 7, wherein the amount changed is in the range of about 0.5 percent based on a total weight of the product.
9. The method of claim 4 in which the inactive ingredient is the disintegrant.

10. The method of claim 9, wherein the amount changed is in the range of about 3 percent based on a total weight of the product.

5 11. A system for verifying the authenticity of a pharmaceutical product comprising the steps of:
manufacturing more than one batch of a pharmaceutical product, each batch having a reference spectral signature;
inputting each of the reference spectral signatures into a database;
10 scanning a sample pharmaceutical product to produce a scanned spectral signature;
comparing the scanned spectral signature to each of the reference spectral signatures;
and
reporting the results of the comparison, wherein the authenticity of the sample pharmaceutical product is verified by the scanned spectral signature being equivalent
15 to at least one of the reference spectral signatures.

12. The system of claim 11 in which the reference spectral signature and the scanned spectral signature are NIR spectra.

20 13. The system of claim 11 in which the spectral signature of the scanned product is transmitted to a database of spectral signatures of authentic products, the scanned spectral signature is compared to the authentic spectral signatures in the database and reporting the results of the comparison are reported.

25 14. A set of groups of a pharmaceutical product having one or more active ingredients and one or more inactive ingredients, wherein the one or more active ingredients and the one or more inactive ingredients are the same in each group in the set, and an amount of at least one of the one or more inactive ingredients is different in at least one group of the set as compared to the other groups in the set, wherein the amount is
30 detectable in a near-infrared (NIR) spectra of the pharmaceutical product in the at least one group of the set as compared to a near-infrared (NIR) spectra of the pharmaceutical product of the other groups of the set.

15. The method of claim 1, wherein the inactive ingredient whose amount is varied is selected from the group consisting of a filler, a disintegrant, a binder, a lubricant, a glidant, a film coat and combinations thereof.

5 16. The method of claim 15, wherein the inactive ingredient is the filler.

17. The method of claim 16, wherein the amount changed is in the range of about 5 percent based on a total weight of the product.

10 18. The method of claim 15 in which the inactive ingredient is the binder.

19. The method of claim 18, wherein the amount changed is in the range of about 0.5 percent based on a total weight of the product.

15 20. The method of claim 15 in which the inactive ingredient is the disintegrant.

21. The method of claim 20, wherein the amount changed is in the range of about 3 percent based on a total weight of the product.

20 22. A member of a set of groups of a pharmaceutical product having one or more active ingredients and one or more inactive ingredients, wherein the one or more active ingredients and the one or more inactive ingredients are the same in each group in the set, and an amount of at least one of the one or more inactive ingredients is different in at least one group of the set as compared to the other groups in the set, wherein the
25 amount is detectable in a near-infrared (NIR) spectra of the pharmaceutical product in the at least one group of the set as compared to a near-infrared (NIR) spectra of the pharmaceutical product of the other groups of the set.

30 23. The method of claim 1, wherein the inactive ingredient whose amount is varied is selected from the group consisting of a filler, a disintegrant, a binder, a lubricant, a glidant, a film coat and combinations thereof.

24. The method of claim 23, wherein the inactive ingredient is the filler.

25. The method of claim 24, wherein the amount changed is in the range of about 5 percent based on a total weight of the product.

26. The method of claim 23 in which the inactive ingredient is the binder.

27. The method of claim 26, wherein the amount changed is in the range of about 0.5 percent based on a total weight of the product.

28. The method of claim 23 in which the inactive ingredient is the disintegrant.

29. The method of claim 28, wherein the amount changed is in the range of about 3 percent based on a total weight of the product.

30. A method of manufacturing a labeled pharmaceutical product having one or more active ingredients and one or more inactive ingredients comprising modifying the quantity of at least one of the one or more inactive ingredients in a first pharmaceutical product to make a second pharmaceutical product, wherein the modification is detectable in a near-infrared (NIR) spectra of the second pharmaceutical product as compared to a near-infrared (NIR) spectra of the first pharmaceutical product, wherein said second pharmaceutical product is the labeled pharmaceutical product.

31. A labeling system for a pharmaceutical product having one or more active ingredients and one or more inactive ingredients comprising modifying a quantity of at least one of the one or more inactive ingredients in a first pharmaceutical product to make a second pharmaceutical product, wherein the modification is detectable in a near-infrared (NIR) spectra of the second pharmaceutical product as compared to a NIR spectra of the first pharmaceutical product, wherein said second pharmaceutical product comprises the label.

32. A method of determining the identify of a pharmaceutical product comprising the steps of:
obtaining a product signature of said pharmaceutical product and

comparing said product signature to a reference product signature of a reference pharmaceutical product, wherein said reference product signature is a member of a library, wherein the pharmaceutical product is identified as the reference pharmaceutical product if the product signature of the pharmaceutical product is the same as the reference product signature.

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